

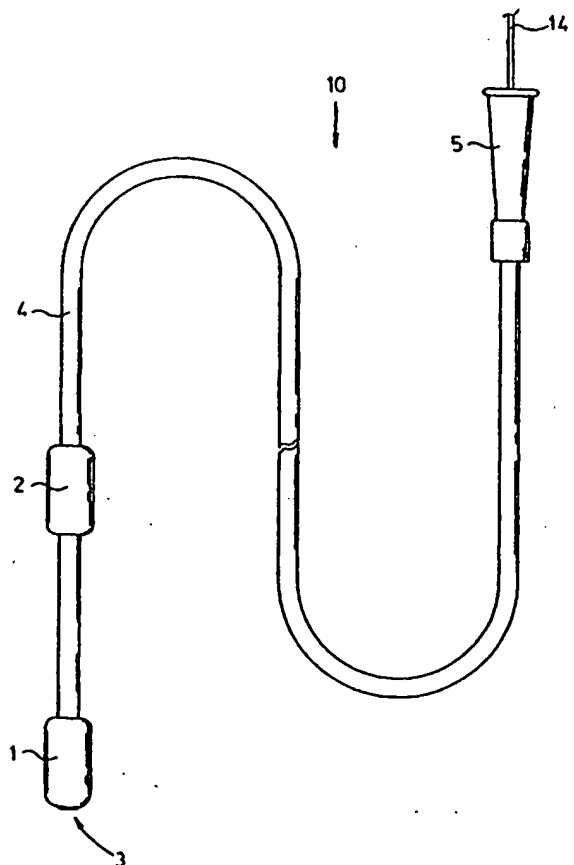


INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁷ : A61J 15/00	A1	(11) International Publication Number: WO 00/53146 (43) International Publication Date: 14 September 2000 (14.09.00)
(21) International Application Number: PCT/NL00/00140 (22) International Filing Date: 3 March 2000 (03.03.00) (30) Priority Data: 1011474 5 March 1999 (05.03.99) NL (71) Applicants (for all designated States except US): STEEN, Harry [NL/NL]; Dalmsholterdijk 6, NL-8146 PG Dalmsholte (NL). TAUBERT, Ulrich [DE/DE]; Siemenstrasse 3, D-48341 Altenberge (DE). (71)(72) Applicant and Inventor: PLOEM, Sven [NL/NL]; Kouwenberg 54, NL-5431 GZ Cuijk (NL). (74) Agent: JORRITSMA, Ruurd; Nederlandsch Octrooibureau, Scheveningseweg 82, P.O. Box 29720, NL-2502 LS The Hague (NL).		(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i> <i>In English translation (filed in Dutch).</i>

(54) Title: SELF-POSITIONING CATHETER**(57) Abstract**

Catheter (10) provided with a flexible catheter tube (4) having a tip (3) of the catheter tube (4) to be introduced into the small intestines of humans or animals, the tip (3) being provided with an engagement body (1; 2) on which the peristalsis of viscera is able to engage in order to introduce the catheter (10). The engagement body is formed by at least one thickening (1; 2) provided with a bore which is in communication with the catheter tube (4). Preferably, two thickenings (1, 2) having a certain weight are attached, as a result of which an effective, as it were automatic, introduction of the catheter (10) is produced by a combination of gravity and engagement of gastric and intestinal peristalsis on the thickenings (1, 2).

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Self-positioning catheter

The present invention relates to a catheter comprising a flexible catheter tube having a tip of the catheter tube to be introduced into the small intestines of humans or animals, the tip being provided with an engagement body on which the peristalsis of intestines is able to engage in order to introduce the catheter.

Such a catheter is used, for example, when administering nutrition, collecting samples from the small intestines for analysis, administering a contrast agent for X-ray diagnosis and administering medicines.

10 The publication WO 98/33469 discloses a catheter for providing liquid communication with the small intestines, the catheter tip forming an engagement body, as a result of which the catheter is as it were automatically introduced by the peristalsis of the intestines. The catheter comprises a tube which has to be introduced into the small intestines via the stomach and has an open input section and an open output section. The output section of the tube has a
15 natural tendency to form a spiral and this output section can be held straight during introduction by means of a guide movable in the tube. When the catheter has been introduced into the stomach, the guide is slid back, as a result of which the output section assumes a spiral shape again. The catheter will then be further introduced by the gastric and intestinal peristalsis. The output section is provided with a capping plug which is provided with holes
20 at the side to allow food to pass through. However, the capping plug is not of sufficient size to be engaged by the gastric and/or intestinal peristalsis. Patent application WO 98/33469 indicates that the capping plug can be provided with contrast agent in order to be able to determine the position thereof with the aid of X-ray diagnosis. Furthermore, the output section of the catheter is provided with hairy projections or fins, by means of which the
25 catheter stays better in place after it has been introduced.

The disadvantage of this catheter is that considerable time is needed before the catheter has been brought into the correct position, in the majority of cases between eight and twelve hours. A further disadvantage of the use of this catheter and method for the introduction of the catheter is that a trained person is needed for introduction of the catheter. The position of
30 the catheter tip has to be checked by, for example, pH measurements of samples obtained via the catheter tip. Frequently, the precise position of the catheter tip has to be verified during or after introduction using, for example, X-ray diagnosis, carried out by a specialist, as a result of which the treatment becomes even more expensive. The procedure for introduction of the

catheter is frequently unpleasant for the patient because the catheter as it were has to be pushed into its final position.

The aim of the present invention is to provide a catheter that can be introduced into the small intestines (duodenum or small intestine) quickly, with little inconvenience to the patient and without the use of additional aids. Furthermore, it must be possible to produce the catheter simply and economically, so that it is suitable for disposable use. Disposable use of medical aids such as the catheter of the present invention is an important requirement in connection with transmittable conditions such as AIDS.

This aim is achieved by means of a catheter of the type defined in the preamble, characterised in that the engagement body is formed by at least one thickening provided with a bore which is in communication with the catheter tube.

Said catheter has the advantage that the thickening at the tip of the catheter tube offers adequate grip for the peristalsis in the stomach. If there is no peristaltic movement in the stomach, the weight and/or the volume of the thickening will stimulate the stomach sufficiently to produce peristalsis in the stomach. As a result, the tip of the catheter tube is, as it were, automatically guided to the transition from the stomach to the duodenum and the catheter tube is then further guided by the intestinal peristalsis. Trials have demonstrated that the catheter according to the present invention is positioned correctly in approximately fifteen minutes, without the use of additional aids. Furthermore, the catheter in question can be produced simply and economically, as a result of which it is suitable for disposable use.

It is pointed out that Japanese Patent JP-08-098889 discloses a catheter provided with a guide piece at the introduction tip. The guide piece comprises a multiplicity of polyhedra which are positioned in a single row, have a relative density of 1.0 or more and are surrounded by an elastic film, as a result of which a rough surface is produced. Because the guide piece as it were consists of articulated parts, the guide piece is easily able to change direction. Because the polyhedra are held together by the elastic film, a rough surface is produced which provides sufficient grip for the peristalsis of the intestines, by means of which the catheter is drawn into the body. However, the guide piece has to be produced separately and attached to the catheter. Furthermore, the guide piece is a closed body, as a result of which the outlet opening of the catheter tip is located behind this body and the catheter and guide piece have to be introduced much further into the body.

A further catheter is disclosed in the article entitled "A Modified Technique for Bedside Placement of Nasoduodenal Feeding Tubes" by J. Davis et al., Journ. of the

American College of Surgeons, April 1994, vol. 178, pp. 407-409. This article describes a technique for introducing a feeding catheter into the duodenum of a patient. With this technique use is made of a feeding catheter having a weighted catheter tip. It is pointed out in the article that this weighted catheter tip is not really satisfactory for rapid introduction of the catheter, even if the patient is brought into a certain position ("right lateral decubitus position"), by means of which the weighted catheter tip can be moved by gravity towards the pylorus. The catheter is introduced into the patient with the aid of a metal guide which is mounted in the catheter and is bent at an angle of 30-45° approximately 2 - 3 cm from the tip. When the catheter tip with the bent guide protruding therefrom is located in the stomach, a rotary movement is made to enable the pylorus to be found. In this way the person introducing the catheter is able to bring the catheter tip into the duodenum by feel. According to the article, the time needed to introduce the catheter is on average 27.5 minutes, with a maximum required time of up to 90 minutes.

In one embodiment of the catheter according to the present invention the at least one thickening is positioned at least partially around the catheter tube. This positioning of the thickening makes simple, and thus inexpensive, production of the catheter possible.

According to one embodiment of the present invention, the cross-section of the thickening is between 0.5 cm and 2 cm in order to guarantee good engagement by the gastric and/or intestinal peristalsis.

In a further embodiment the dimension of the at least one thickening along the catheter tube is so small that the catheter tube remains flexible.

Preferably, the weight of the at least one thickening is between 5 and 20 gram, for example 11 gram, so that when the patient is in the correct position the tip of the catheter, on introduction, follows the stomach wall to the pylorus. This speeds up the introduction of the catheter even more.

Preferably, the at least one thickening consists of a metal body, for example made of stainless steel, mounted around the catheter tube. Such a catheter is simple and economical to produce, having due regard for the requirements in respect of dimensions and weight. If verification of the position of the tip of the catheter is desired, this is simple to achieve with the aid of X-ray diagnosis, the metal body being clearly detectable. As an alternative, the at least one thickening can consist of a balloon filled with liquid.

In a preferred embodiment the at least one thickening has a flat oval shape. This shape makes a combination of the abovementioned characteristics possible in an efficient manner,

that is to say that the thickening has a limited diameter, length and weight. Furthermore, the least inconvenience to the patient is to be expected with this shape.

In a further embodiment the at least one thickening forms a smooth front limit of the catheter. A catheter which can be introduced very efficiently is produced by making the
5 thickening as far as possible at the tip of the catheter.

In one embodiment of the present invention the distance between two successive thickenings is a physiologically determined distance. The distance is determined by the anatomical relationships at the pylorus, so that an effective pull-push mechanism is produced by engagement of the intestinal wall on the first thickening and of the stomach wall on the
10 second thickening. The distance is between 2.5 and 10 cm and is, for example, 6 cm for an average adult male.

A second aspect of the present invention relates to a method for the introduction of a transnasal catheter, which is known per se, with the aid of the transoral catheter according to the present invention. The method comprises the steps of transoral introduction of the
15 catheter until the tip of the catheter is in a desired position, the transnasal introduction of a transnasal catheter and bringing the transnasal catheter back to the outside through the mouth, the introduction of a guide wire into the catheter and fixing the guide wire in the correct position, withdrawal of the transoral catheter, the guide wire remaining in the fixed position, the introduction of the guide wire into that section of the transnasal catheter which is
20 protruding from the mouth, feeding the tip of the transnasal catheter back into the throat and introduction of the transnasal catheter along the guide wire into the desired position.

The present invention will now be further explained on the basis of a description of a preferred embodiment of the present invention with reference to the appended drawing, in which

25 Fig. 1 shows a diagrammatic view of a catheter according to the present invention;

Fig. 2 shows a sectional view of the tip of one embodiment of the catheter according to the present invention;

Fig. 3 shows a sectional view of the tip of a further embodiment of the catheter according to the present invention;

30 Fig. 4 shows a sectional view along the line IV-IV in Fig. 2; and

Fig. 5 shows a sectional view of the tip of yet a further embodiment of the catheter according to the present invention.

Fig. 1 shows a diagrammatic view of a catheter 10 according to the present invention.

The catheter 10 consists of a long, flexible tube 4 with a connector 5 at one end. The tip 3 at the other end of the flexible tube 4 can be introduced via the mouth of a patient into the small intestines, such as the duodenum or the small intestine. The catheter 10 introduced can be used for administering nutrition, collecting samples from the small intestines for analysis, administering contrast agent for X-ray diagnosis, administering medicines, etc.

According to the embodiment of the present invention shown, a thickening 1 is arranged around the tip 3 of the catheter 10, the cross-section of which thickening 1 is appreciably greater than the cross-section of the flexible tube 4. The thickening 1 is provided with a bore which is in communication with the flexible tube 4. Preferably, the thickening 1 forms the front limit of the catheter 10. In a preferred embodiment of the present invention, a second thickening 2 is also arranged around the flexible tube 4, at a first distance from the first thickening 1. The thickenings 1, 2 can be made from the same material as the flexible tube 4, as a result of which the catheter 10 is simple to produce. In a preferred embodiment the thickenings are formed by bodies of a different material, such as stainless steel, arranged around the flexible tube 4. The thickenings 1, 2 preferably have a cylindrical shape or flat oval shape and are fixed on or to the outside wall of the flexible tube 4. As an alternative, the thickenings can be formed by balloons which are arranged on the outside of the flexible tube 4 and can be filled with a liquid, for example water.

Fig. 2 shows a sectional view of the tip of an embodiment of the catheter 10 according to the present invention. With this embodiment the thickenings 1, 2 are constructed as hollow cylinders 1, 2 which have a central bore which corresponds to the outside diameter of the flexible tube 4. This embodiment is very simple to produce by sliding the cylinders 1, 2 over the tip 3 of the flexible tube 4 and fixing in the correct position, for example with the aid of adhesive.

Fig. 3 shows a sectional view of the tip of a further embodiment of the catheter 10 according to the present invention. With this embodiment the thickenings 1, 2 constructed as cylindrical bodies are used as connecting pieces between sections of the flexible tube 4, 4a. In this case the central bore of each of the cylindrical bodies 1, 2 is preferably the same size as the inside diameter of the flexible tube 4, 4a. The cylindrical body 1 located at the tip 3 of the catheter has a further bore for accommodating the section of the flexible tube 4a. The second cylindrical body 2 has a further bore at either end for accommodating the ends of the flexible tube 4 and the section of the flexible tube 4a.

Fig. 4 shows a sectional view of the catheter 10 at the line IV-IV in Fig. 2. This view

clearly shows that the thickening 2 is arranged around the flexible tube 4.

Fig. 5 shows a sectional view of the tip of yet a further embodiment of the catheter 10 according to the present invention. In this embodiment the thickenings 1, 2 are provided with a fitting flange over which the flexible tube 4 can be pushed for fixing. The fixing can be held
5 in place with the aid of a suitable adhesive. This fitting flange is simple to produce in the thickenings 1, 2 by a milling operation. The advantage of this embodiment is that the thickenings can be kept of maximum volume, as a result of which the weight of the thickenings 1, 2 can remain as high as possible.

In a preferred embodiment the thickenings 1, 2 have a cross-section of between 0.5 cm
10 and 2 cm, for example 1 cm. The cross-section of the thickenings 1, 2 must be of a minimum size to ensure that engagement by the peristalsis in the stomach and/or the intestine can take place. On the other hand, the cross-section of the thickening 1, 2 must not give rise to any problems when introducing the catheter 10.

In the embodiments shown the thickenings 1, 2 have a maximum dimension along the
15 flexible tube 4 such that the flexibility of the flexible tube 4 which is required in order to be able to introduce the catheter 10 easily remains ensured.

When the catheter 10 is introduced via the mouth of a patient, the weight of the thickenings 1, 2 will ensure that the tip 3 of the catheter 10 moves easily downwards into the stomach. As a result of the patient being in the correct position (lying on the right-hand side),
20 the tip 3 of the catheter will move towards the pylorus. The weight of the thickening is preferably between 5 and 20 gram and is, for example, 11 gram. At the pylorus the gastric peristalsis will engage on the first thickening 1. As a result the tip 3 of the flexible tube 4 is, as it were, automatically pushed towards the pylorus.

When the first thickening 1 is beyond the pylorus in the duodenum, it will be engaged
25 there by the intestinal peristalsis. At the same time the second thickening 2 will still be engaged by the gastric peristalsis, as a result of which as it were a double effect arises and the tip 3 of the flexible tube 4 is pulled or pushed further into the small intestine. As a result of the combination of the engagement of gastric and/or intestinal peristalsis, combined with the effect of gravity, an exceptionally rapid, automatic positioning of the catheter 10 takes place.
30 In order to achieve such an effective push-pull mechanism, the distance between the first thickening 1 and the second thickening 2 must be of a certain size, which is determined by the anatomical relationships at the pylorus of the patient. Preferably, the distance from the first thickening to the second thickening is between 2.5 and 10 cm. The distance can be, for

example, 6 cm for use of the catheter 10 for an adult patient.

By means of distance markings on the flexible tube 4, a measure which is known per se, it is possible to establish that the catheter has been positioned far enough into the small intestines, after which the catheter can be fixed in place. After fixing, the distance markings
5 can be used to check that the position of the catheter 10 has not changed.

The catheter 10 according to the present invention has been tested in practice and it has been found that no longer than fifteen minutes are needed to bring the catheter into the correct position, whilst the discomfort for the patient remained very limited, certainly in comparison with catheters used to date. With the aid of X-ray diagnosis it has been demonstrated that
10 during introduction the thickenings 1, 2 of the catheter 10 are indeed engaged by the gastric and intestinal peristalsis.

Although the cross-section of the thickenings 1, 2 restricts the use of this catheter 10 to transoral introduction of the catheter 10, it is possible to use the transoral catheter 10 in a method for the introduction of a transnasal catheter. In general a transnasal catheter is
15 preferred if the catheter has to be present for a prolonged period.

First of all the catheter 10 according to the present invention is introduced transorally into the desired position in the small intestines. A transnasal catheter is then introduced via the nose, which catheter is fed back to the outside through the mouth, for example using McGill forceps. A guide wire 14 (see Fig. 1) is introduced through the correctly positioned
20 catheter 10 into the small intestine. The guide wire 14 is then fixed in place, so that the catheter 10 can be removed again while the guide wire 14 remains in the desired position. For this purpose the catheter 10 must, of course, be open at its front limit. That portion of the guide wire 14 protruding from the mouth of the patient is then fed through the transnasal catheter until it protrudes outwards through the nose. The transnasal catheter can now be fed
25 back into the pharynx, so that the transnasal catheter can be guided over the guide wire 14 into the small intestine.

Claims

1. Catheter comprising a flexible catheter tube having a tip of the catheter tube to be introduced into the small intestines of humans or animals, the tip being provided with an engagement body on which the peristalsis of intestines is able to engage in order to introduce the catheter, characterised in that the engagement body is formed by at least one thickening (1; 2) provided with a bore which is in communication with the catheter tube (4).

2. Catheter according to Claim 1, characterised in that the at least one thickening (1; 2) is positioned at least partially around the catheter tube (4).

3. Catheter according to Claim 1 or 2, characterised in that the cross-section of the at least one thickening (1; 2) is between 0.5 cm and 2 cm.

4. Catheter according to Claim 1, 2 or 3, characterised in that the dimension of the at least one thickening (1; 2) along the catheter tube (4) is so small that the catheter tube (4) remains flexible.

5. Catheter according to one of the preceding claims, characterised in that the weight of the at least one thickening (1; 2) is between 5 and 20 gram.

6. Catheter according to one of the preceding claims, characterised in that the at least one thickening (1; 2) consists of a metal body.

7. Catheter according to one of Claims 1 to 5, characterised in that the at least one thickening (1; 2) consists of a balloon filled with liquid.

8. Catheter according to one of the preceding claims, characterised in that the at least one thickening (1; 2) has a flat oval shape.

9. Catheter according to one of the preceding claims, characterised in that the at least one thickening (1; 2) forms a smooth front limit of the catheter (10).

10. Catheter according to one of the preceding claims, characterised in that the distance between two successive thickenings (1; 2) is a physiologically determined distance.

11. Catheter according to Claim 10, characterised in that the physiologically
5 determined distance is determined by anatomical relationships of the pylorus.

12. Method for introducing a transnasal catheter with the aid of a catheter according to one of Claims 1 to 11, characterised in that the method comprises the following steps:

- 10 - the transoral introduction of the catheter (10) until the tip (3) of the catheter (10) is in a desired position,
- the transnasal introduction of a transnasal catheter and bringing the transnasal catheter back to the outside through the mouth,
- the introduction of a guide wire (14) into the catheter (10) and fixing the guide wire (14) in the correct position,
- 15 - withdrawal of the transoral catheter (10), the guide wire (14) remaining in the fixed position,
- the introduction of the guide wire (14) into that section of the transnasal catheter which is protruding from the mouth,
- feeding the tip of the transnasal catheter back into the throat,
- 20 - introduction of the transnasal catheter along the guide wire (14) into the desired position.

fig-1

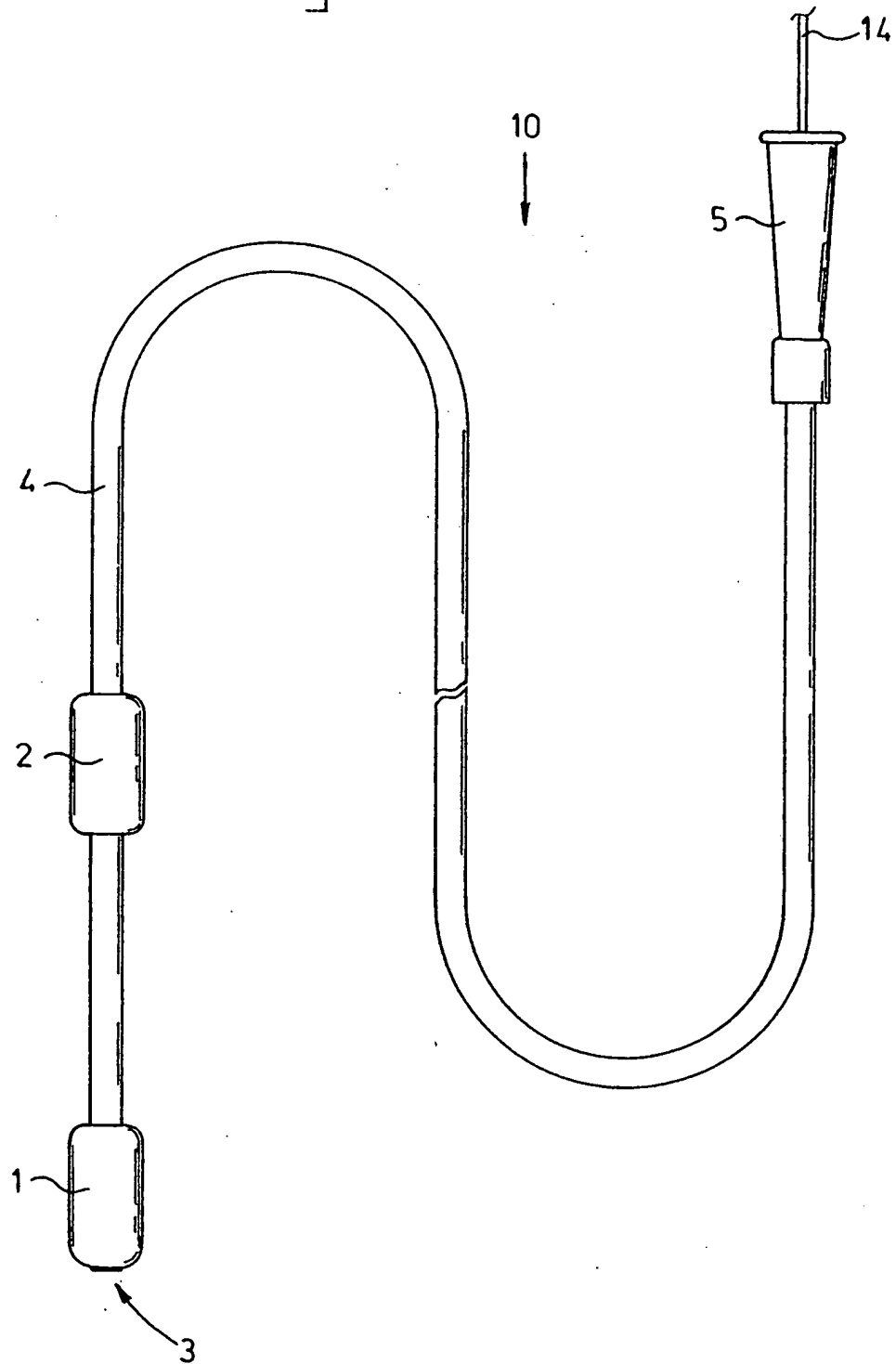


fig - 2

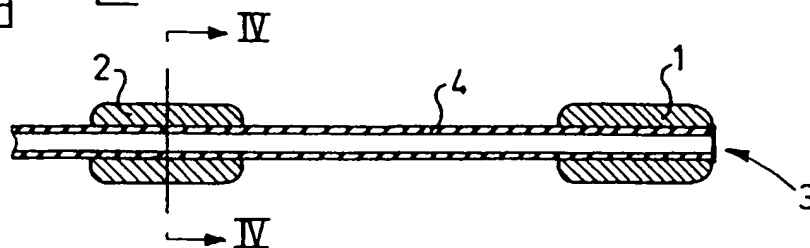


fig - 3

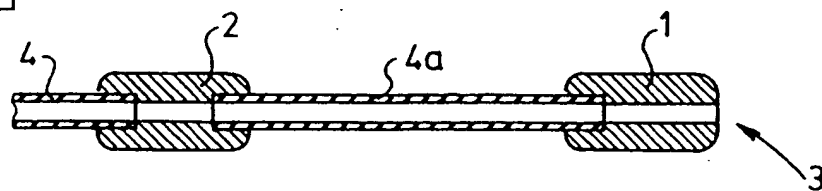


fig - 4

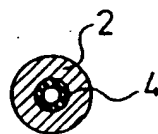
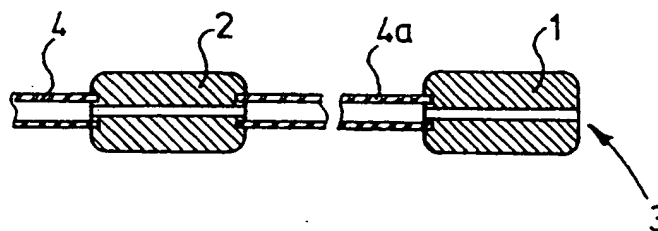


fig - 5



INTERNATIONAL SEARCH REPORT

Inter: vna! Application No

PCT/NL 00/00140

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61J15/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61J

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	DE 35 09 067 A (STERIMED GMBH) 26 September 1985 (1985-09-26) page 5, line 4 - line 19; claims; figures 1,2,5 page 6, line 30 - line 36 page 7, line 29 -page 8, line 9	1,2,4-6, 8 3,10,11
X	EP 0 191 471 A (TERUMO CORP) 20 August 1986 (1986-08-20) page 3, line 31 -page 4, line 12; figure 5	1-5,8,9
A	US 4 631 054 A (KIM IL G) 23 December 1986 (1986-12-23) column 2, line 53 - line 64; figure 1	7
	-/-	



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

*** Special categories of cited documents :****"A"** document defining the general state of the art which is not considered to be of particular relevance**"E"** earlier document but published on or after the international filing date**"L"** document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)**"O"** document referring to an oral disclosure, use, exhibition or other means**"P"** document published prior to the international filing date but later than the priority date claimed**"T"** later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention**"X"** document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone**"Y"** document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.**"&"** document member of the same patent family

Date of the actual completion of the international search

30 May 2000

Date of mailing of the international search report

07/06/2000

Name and mailing address of the ISA

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INTERNATIONAL SEARCH REPORT

International Application No.

PCT/NL 00/00140

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 98 33469 A (BENCHMARK STIG) 6 August 1998 (1998-08-06) cited in the application abstract; figures	1
A	PATENT ABSTRACTS OF JAPAN vol. 096, no. 008, 30 August 1996 (1996-08-30) & JP 08 098889 A (SANMOA:KK), 16 April 1996 (1996-04-16) cited in the application abstract	1

INTERNATIONAL SEARCH REPORT

Int. application No.

PCT/NL 00/00140

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/NL 00/00140

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
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